Developing a Practice-Based Research Network by Integrating Quality Improvement: Challenges and Ingredients for Success

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Abstract

Improving patient outcomes in community-based settings is the goal of both the Clinical Translational Science Award program and practice-based quality improvement (QI) programs. Given this common goal, integrating QI and outcomes research is a promising strategy for developing, implementing, and evaluating clinical interventions. This article describes the challenges and strengths illuminated by the conduct of a combined research/QI study in a nascent practice-based research network. Challenges include research's exclusion of clinic patients who might benefit from the intervention; QI programs' less uniform approach to intervention implementation; and the need for both academic and clinically relevant products and publications. A major strength is the increased likelihood of both engaging clinical practices in research and developing successful clinical interventions. Required elements for success include identification of enthusiastic clinical research "champions," involvement of researchers with clinical experience, and adequate funding to support both research and clinical resources and dissemination. Combined QI/research projects in the practice-based research environment have the potential to improve and shorten the cycle from good idea to improved clinical outcomes in real-world settings. Clin Trans Sci 2012; Volume 5: 351–355

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Introduction

A fundamental long-term goal of the Clinical Translational Science Award (CTSA) program is to improve patient outcomes for typical patients in community practice settings by speeding the often slow and ineffective translation of research findings into practice.[1,2] Improving patient outcomes has also been the focus of practice-based quality improvement (QI) programs,[3] suggesting that integrating QI and outcomes research holds promise for implementing and disseminating successful interventions.[4,5] Despite commonalities between QI and research, there are also differences.[6,7] Unlike research, QI programs generally do not employ rigorous and more time-consuming research methodologies that support generalizing the interventions and results to other practices. Research emphasizes discovery, whereas QI focuses on application, such as systems change and clinical outcomes.[8] Also, research is designed to produce new knowledge, whereas QI generates knowledge to address an internal organizational concern.[9]

Developing a practice-based research network (PBRN) with a model that integrates research and QI builds on the existing strengths of QI efforts, adding research incrementally rather than building a research program from the ground up. PBRNs provide an avenue for bringing research into practice[2,7] and encourage a collaborative approach between researchers and clinicians.[10] Participatory approaches that combine QI and research are more likely to be relevant, tailored, and actionable to practitioners. Clinical practices may be more likely to engage in research that directly affects their patient care mission. Moreover, clinicians who participate in knowledge generation may be more likely to adopt the research results.[2,8]

To advance the integration of QI and research in PBRNs, we present a case study of a combined research/QI intervention in a nascent primary care PBRN, illuminating differences in research and QI methods as well as the challenges and strengths of the combined approach. This description of the key elements and measures of success for the integrated model may inform investigators considering this approach.

Case Study

As part of an effort by the Community Outreach and Research Translation Core of the University of Washington's CTSA (the Institute of Translational Health Sciences, ITHS) to build a PBRN in Washington, Wyoming, Alaska, Montana, and Idaho, seven clinical practices in the University of Washington's (UW) Family Medicine Residency Network (FMRN) participated in a study of clinical importance to the practices that simultaneously built research capacity and infrastructure at the sites. There was timely synergy between the CTSA efforts and the UWFMRN's strategic plan to increase its research capacity and participation, providing fertile ground.

The ITHS's Community Outreach and Research Translation Core coordinated the project and provided support for key research functions, such as completion of Institutional Review Board (IRB) applications at the clinical sites. The clinical sites provided personnel who conducted study procedures on-site (e.g., physicians, QI staff, trainees), including submission of the IRB application and chart abstraction, and directed the QI intervention. Because this study fulfilled one of the UWFMRN's strategic goals, it allocated pilot funds to this study, as did the UW Department of Family Medicine. These funds were used to support data analysis.

The research focused on two questions:

Among women able to bear children who had active prescriptions for common medications with potential adverse fetal effects (angiotensin converting enzyme inhibitors [ACE-Is], angiotensin II receptor blockers [ARBs], and HMG-CoA reductase inhibitors [statins]):

(1) What contraceptive methods were used?
(2) What proportion had documented informed consent or acknowledgment of the adverse fetal effects of these medications?

Data were collected using two chart reviews: the first gathered data on study exclusion/inclusion criteria, contraceptive methods,

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	QI focused	Research focused	Combined QI and Research
Goal	Improve quality of clinical care.	Generate new knowledge.	Contribute to new knowledge while improving clinical care and patient health outcomes in research sites. Discovery is directly linked to the context in which it is tested.
Study population	Seeks to include the largest possible group that might be affected by the health concern.	Inclusion and exclusion criteria are used to ensure a specific and narrowly identified research population.	Largest possible group identified so QI intervention has major impact. Research procedures conducted only on a subset of the QI population.
Design	Procedures may be tailored to individual clinic circumstances.	Highly standardized approach across multiple and diverse sites.	Allows for rigor of standardized research design but ensures that the research meets principal clinic mission of improving patient care.
Implementation	Clinic leader creates project protocol. No external regulatory processes are needed, such as Institutional Review Board approval and informed consent. Procedures can change if original plan ineffective.	Researcher creates research protocol. Must meet Institutional Review Board standards, including consent. Adherence to strict protocol.	Researcher and clinic leaders create the research protocol collaboratively. Clear separation of QI and research processes. Providers cannot act as researchers (e.g., in consent process).
Analysis	Straightforward descriptive analysis is usually sufficient. May change if needs or interests change. Statistical significance irrelevant.	Determined in advance by study design. Interpretation of findings dependent on their statistical significance.	Research analysis primary. Additional analyses driven by clinic needs and conducted for providers and administration.
Dissemination	Feedback on maintenance and sustainability solicited from the clinic/clinic system. Dissemination/widespread application within the clinic/clinic system.	Publication in peer-reviewed journal.	Dissemination plan includes both peer-reviewed publications as well as a plan for sustaining successful changes at the clinic level. Plan for dissemination beyond the research settings into practice crucial.
Personnel	Administrative and clinical leads from within the clinic/clinic system.	Traditional research investigators and staff.	Research team includes clinician research "champions" from the clinical sites alongside research investigators. Funding is required for clinic personnel conducting unique research functions.
Expertise needed	Clinical practice/patient care. Clinic systems. Systems change.	Regulatory processes (e.g., IRB). Human subjects training. Research methods and conduct. Statistical expertise.	Expertise as noted for both QI and research projects. Expertise in dissemination of successful interventions across diverse clinical settings. Clinical site leaders participate in regulatory processes and must be human subjects trained.
Organizational support	Clinic and health systems.	Research institution/s.	Linked research institutions and clinic/health system. Established practice based research network ideal.
Funding	Existing clinical administrative and operational budgets	Grant funding (e.g., NIH, foundations)	Grant funding, including budget items that support clinic resources and personnel involved in research. Clinic-funded QI infrastructure provides core existing resource and expertise.

Table 1. Comparison of quality- and research-focused approaches.

and informed consent; the second, at least 2 months after a QI intervention, gathered data on documentation of informed consent and change in ACE-I, ARB, and statin medications and/or contraceptive methods. The study received IRB approval from the UW and from each participating site.

Between the two chart reviews, the practices implemented a QI intervention with patients identified as potentially at risk for adverse fetal effects: those without surgical sterilization and without documentation of informed consent. Although the research team provided written materials and guidance that clinics could use for QI design, each practice designed its own QI intervention to fit local circumstances. Common to each QI intervention was the practice of contacting the patients individually to discuss the benefits and risks of the medications with potential adverse fetal effects, and to determine whether to make medication or contraception changes.

The research study protocol and materials were developed by a steering committee and advisory council that included UW academic researchers and health care providers from participating sites. Engaging clinical providers in study design ensured inclusion of elements that directly benefited clinical practice as well as supported a methodologically sound research study.

Findings

Throughout the project, we noted where the QI or research focus illuminated similarities and differences of the two approaches, summarized in *Table 1*. Here we selectively present illustrations of how we combined features of QI- and research-focused approaches in our case study's project.

Definition of the study population

The research protocol defined eligible women as ages 18–44 years; premenopausal; with a diagnosis of hypertension, diabetes, or hypercholesterolemia; and with one or more active prescriptions for ACE-Is, ARBs, or statins. This strict sample definition excluded

some at-risk women using these medications who qualified for QI. Individual clinics chose to cast a wider net in identifying women for the QI intervention. The research team then used chart abstraction information to exclude women who did not qualify for the research.

Study design and implementation

Avoidance of potential research protocol contamination by the QI intervention

Because an important goal of a combined QI/research project was to address the clinic's patient care mission as well as the research questions, we solicited input from clinical site leaders throughout study design and implementation. However, we were concerned that this substantive discussion of research procedures with clinicians might introduce contamination of the baseline research findings. Materials and information provided to clinical site leaders and other providers before study implementation could have sensitized providers to the medication risks that were the topic of this research, and led to practice change before the implementation of the QI intervention. We worked closely and rapidly with clinical site leaders to schedule information provision to clinic providers in a way that minimized its effect on baseline data while allowing a timely QI intervention. Separation of the research procedures and the clinic-initiated QI intervention meant that the research team did not fully control time lags between study design and implementation.

IRB consideration in a multisite study

IRB processes were a rate-limiting step in most practices, and proved insurmountable in some. At our sites, local IRB members sometimes had little primary care clinical background, and some were unaware of clinical care standards. Widely accepted clinical care procedures and operations raised red flags or seemed risky to some IRBs examining them under a research lens. For this reason, we separated the QI intervention from the research protocol. In particular, nonacademic IRBs (e.g., community hospital-based) raised more concerns with issues of liability and clinical accountability. In these settings, separating the research and QI components may have improved the likelihood of approval.

Lack of uniform approach to QI interventions

Separating the research and QI intervention allowed each clinic to develop its own approach, but the consequence was lack of uniformity in the QI process, which likely contributed to uneven implementation. Only 50% of at-risk patients had documentation that they received the QI intervention, with variability between sites. The project design did not allow us to identify whether problems with QI implementation were systemic in a site or related to certain providers. In general the QI interventions depended on individual discussions and problem solving between providers and patients, only one of several available QI strategies.[11–14] This draws attention to the importance of research on effective QI methods, another role for combined research/QI projects, but beyond the scope of this project.

Analysis and dissemination

A research team generally focuses on analysis of aggregated data across clinics to support a peer-reviewed publication, aiming to disseminate successful interventions through the journal readership or through replication of the findings elsewhere. As a result of our combined QI/research project, we have developed this commentary and two traditional manuscripts for publication in peer-reviewed journals, one in press reporting the results of a qualitative analysis of medication prescription and refill practices at the seven clinical sites,[15] a second under development that reports the clinical results of the project. The project also funded several site partners to present this work at national academic conferences. However, successful dissemination also included presentations at regional meetings of the developing PBRN and the UWFMRN Directors, as well as immediate feedback to clinic providers about individual clinic performance. Thus, the analysis plan included simultaneous analyses of individual clinics' data and of the aggregated research data across clinics. Academic investigators worked alongside clinic leaders to design and produce individualized clinic analyses in a format of greatest interest and utility to the clinics.

Discussion

Essential and desirable elements for combined QI/research project success

Our study of ACE-Is, ARBs, statins, and contraception has helped us better understand issues arising in a combined QI/research project, identifying what we believe are required elements for success. These include:

(1) Finding clinical research champions enthusiastic about engaging in the development of combined QI/research. Given the demands of clinical practice, engagement of these champions and their clinics requires that they experience rewards from this work. These rewards may result from fulfillment of another professional role, such as QI coordinator. We also found that a clinic's participation in research and in pioneering innovation in clinical practice can serve as an important tool to recruit providers to the practice and retain them, an unanticipated outcome of this work.
(2) Involving research leaders who have clinical experience. The credibility of a combined QI/research enterprise requires that the research is responsive to clinical demands and constraints, and that the QI component responds to research demands for scientific rigor. Having one or more individuals comfortable with and accountable in both domains proved important for overall success.
(3) Adequate funding and time to address the dual goals of QI and research. Our pilot project received support from academic and clinical sources. Full scale combined QI/research projects require grant funding that support research personnel and procedures, as well as clinical resources and personnel participating in the research. Dissemination of these combined projects is also twofold, involving both peer-reviewed publications and clinic-based reporting. In our project, providing reports that the research champions could present to their clinical colleagues was an essential dissemination strategy that furthered the QI process and promoted sites' interest in research participation.

We also identified desirable elements that promote the success of a combined QI/research project.

(1) Team expertise with a range of ambulatory clinical settings (e.g., small private practices, community health centers, hospital-based clinics).

(2) Research team flexibility to incorporate clinic QI methods into its research protocols.
(3) A clinical research network with experience in implementing QI interventions, and a willingness to be involved in sequential projects that develop expertise in both QI and research domains.
(4) Electronic health record (EHR) systems that facilitate patient identification for research, gather data for research, and advance QI. The capability of the EHR to support point-of-care clinical decision support tools can advance QI and support research protocols that test evidence-based interventions.

Measures of success for combined QI/research projects

The long-term goal of combined QI/research is to demonstrably improve the health of the population within clinical practices. Other benefits accrue in the short and intermediate term to researchers, to practices, and to practice providers. The success of combined QI/research can be measured initially by these short and intermediate steps on the path to the long-term outcome of improved population health. The long-term goals of stimulating research interest and a culture of scientific inquiry as well as developing research capacity at participating clinical sites likely would not have been achieved without the addition of QI. Clinical sites are more likely to participate in research that involves QI because they feel that it has potential for immediate value to patients, unlike most research.

Practices and practice providers

Research tools and procedures can support practices and their clinical efforts at the same time that they attend to research processes. Success of a combined QI/research project also can be measured by a practice or provider acquisition of new skills and resources applicable to practice operations.[16,17]

(1) In the ACE-Is, ARBs, statins, and contraception study, practices participated in development of the study's chart abstraction tool, a capability fundamental to the success of other QI projects.
(2) Several practices had not previously leveraged their EHR or billing data to identify a population of patients for QI, a new capacity built by this project and essential to the conduct of many QI-only projects as well.
(3) The described project significantly advanced the PBRN's goal of linking practices electronically using a utility that extracts semantically aligned data from the EHR, and organizes it in a way that promotes both local QI and sharing for the purposes of benchmarking and research. Because this utility is in common with several other PBRNs, our PBRN's electronically connected practices are able to participate in national QI and benchmarking efforts through a federated affiliation called DARTNet.
(4) For residency training programs such as those linked with this study's clinical sites, conducting research helps them meet training requirements. The ACE-Is, ARBs, statins, and contraception study stimulated research interest and developed enduring research capacity in these programs, nurturing their culture of scientific inquiry.
(5) Providers understand and are frustrated by the mismatch between research conducted in academic settings and the applicability to their settings. Contributing to the development of knowledge that is relevant to primary care as it is practiced in community settings is a satisfying experience for providers.

Researchers

The development of research infrastructure within practices and in collaboration with community-based providers is invaluable to meeting researchers' aims of impacting practice and improving population health. New research infrastructure is clear evidence of the success of a combined QI/research project.

(1) In the ACE-Is, ARBs, statins, and contraception study, collaborative research-practice structures, namely steering and advisory committees that included both academic and practice members, provided input into the research design, procedures, and protocols. With the support of these committees, the project had a greater chance of engaging providers and creating a doable protocol. These committees also strengthened relationships between practice leaders and researchers, paving the way for ongoing QI/research collaborations.

The level of collaboration with practices required in a combined QI/research project ensures researchers' insights into the processes of provider and practice behavior change. With better understanding of the barriers and facilitators to practice change, researchers are more likely to develop successful clinical interventions that transform care processes and improve health outcomes.

Conclusions

Combining research with QI interventions holds promise as a method for both speeding the translation of effective interventions into practice and improving strategies at the point of care for implementing these interventions. Our study of ACE-Is, ARBs, statins, and contraception suggests that PBRNs provide excellent environments for such work. Clinical practice leaders must be actively engaged with researchers, ensuring the QI intervention is appropriately integrated with the research methods. Optimally, members of the research team are clinicians themselves and understand the tension between the clinical practice's focus on patient care and research's focus on discovery. Increasingly, clinical systems such as electronic medical records, point-of-care clinical decision support tools, and software to develop clinical registries can support both QI and research functions. Researchers must familiarize themselves with these clinical and QI tools so that they can leverage them effectively in research. The clinical environment is changing rapidly in response to medical home projects and health care reform, demanding flexibility and responsiveness of researchers and clinicians alike as they collaborate on projects. We believe that combined QI/research projects in the PBRN environment have the potential to generate new knowledge in community settings while injecting it more rapidly into routine practice, both improving and shortening the cycle from good idea to improving clinical outcomes.

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